



Dkt. #692-A-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tuo JIN  
U.S. Serial No.: 10/606,344  
Filed Date : June 26, 2003  
For : SOLID DOSAGE FORMS FOR RAPID DISSOLUTION  
OF POORLY SOLUBLE DRUGS

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October 2, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, Applicant would like to direct the Examiner's attention to the following references which are listed below on Forms PTO/SB/08A and PTO/SB/08B (**Exhibit A**), with each individual reference further attached as **Exhibit 1** through **13**.

1. Pather, et al., "Microemulsion as solid dosage forms for oral administration"; US Patent 6,280,770 (2001).  
[**Exhibit 1**]
2. S.C. Mehta, "Issues and approaches for improving the solubility and bioavailability of poorly soluble compounds", *Bulletin Tech., Gattefose*, No. 91, 65-71 (1998). [**Exhibit 2**]
3. D.A. Wyatt, "Taking poorly water soluble compounds through discovery", *Bulletin Tech Gattefose*, No. 92, 31-39 (1999). [**Exhibit 3**]

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Page : 2

4. E. Nelson, *J. Pharm. Sci.*, **47**, 297 (1958). **[Exhibit 4]**
5. E. Nelson, S. Long, J.G. Wagner, *J. Pharm. Sci.*, **53**, 1224 (1964). **[Exhibit 5]**
6. S. Niazi, *J. Pharm. Sci.*, **65**, 302 (1976). **[Exhibit 6]**
7. T.M. Serajuddin, "Physicochemical basis of increased bioavailability of a poorly water-soluble drug during following oral administration of organic solutions"; *J. Pharm. Sci.*, **77**(4), 325-329 (1988). **[Exhibit 7]**
8. A. Sheth, I. Jarowski, "Use of powder solution to improve the dissolution rate of polythiazide tablets"; *Drug Development and Industrial Pharmacy*, **16**(5), 965-977 (1990). **[Exhibit 8]**
9. S.K. Dordunoo, "Preformulation studies on solid dispersions containing triamterene or temazepam in polyethylene glycols or Celucire 44/14 for liquid filling hard gelatin capsules"; *Drug Development and Industrial Pharmacy*, **17**(12), 1685-1713 (1991). **[Exhibit 9]**
10. A.T.M. Serajuddin, "Solid dispersion of poorly water soluble drugs: early promises, subsequent problems, and recent breakthroughs"; *J. Pharm. Sci.*, **88**(10), 1058-1066 (1999). **[Exhibit 10]**
11. B. Lundberg, "A submicron lipid emulsion coated amphipathic polyethylene glycol for parental administration of paclitael", *J. Pharm. Pharmacol.*, **49**, 16-21 (1997). **[Exhibit 11]**
12. D.A. Wadke, A. T. Serajuddin, H. Jacobson, "Preformulation testing"; in *Pharmaceutical Dosage Forms: Tablets*, pg 12-13, Ed. H. A. Lieberman, et al., Marcel Dekker, 1989, New York. **[Exhibit 12]**
13. P.P. Constanides, "Lipid microemulsions for improving drug dissolution and oral absorption: physical and biopharmaceutical aspects"; *Pharm. Res.*, **12**(11), 1561-1572 (1995). **[Exhibit 13]**

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If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

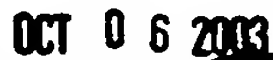
I hereby certify that this paper is being deposited this date with the U.S. Postal Service with sufficient postage for first class mail addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Albert Wai Kit Chan 10/26/03  
Albert Wai-Kit Chan Date  
Reg. No. 36,479

Respectfully submitted,

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Approved for use through 04/30/2003. OMB 0651-0031

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Sheet	1	of	3
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**Complete if Known**

Application Number	10/604,344
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Filing Date	June 26, 2003
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First Named Inventor	Tuo JIN
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Art Unit	1615
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Examiner Name

Attorney Docket Number	692-A-US
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## U. S. PATENT DOCUMENTS

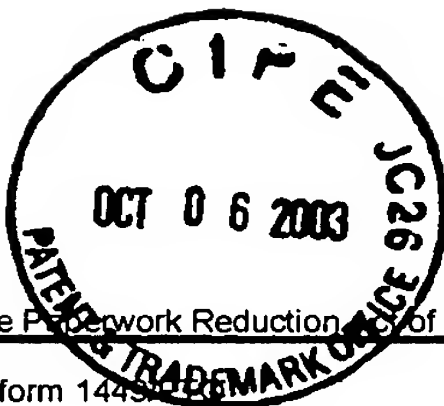
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## FOREIGN PATENT DOCUMENTS

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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STATEMENT BY APPLICANT**

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Application Number

10/604,344

Filing Date

June 26, 2003

First Named Inventor

Tuo JIN

Art Unit

Examiner Name

Sheet

2

of

3

Attorney Docket Number

692-A-US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	2	S. C. Mehta, "Issues and approaches for improving the solubility and bioavailability of poorly soluble compounds", Bulletin Tech., Gattefosc, No. 91, 65-71 (1998).	
	3	D. A. Wyatt, "Taking poorly water soluble compounds through discovery", Bulletin Tech Gattefosc, No. 92, 31-39 (1999).	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Applicant Number	10/604,344
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				Examiner Name	
Sheet	3	of	3	Attorney Docket Number	692-A-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	12	D. A. Wadke, A. T. Serajuddin, H. Jacobson, "Preformulation testing"; in Pharmaceutical Dosage Forms: Tablets, pg 12-13, Ed. H. A. Lieberman, et al., Marcel Dekker, 1989, New York	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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